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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/471,040	12/23/1999	ULF TILSTAM	SCH-1615-D1	6934

23599 7590 01/02/2003

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EXAMINER

OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 01/02/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/471,040

Applicant(s)

TILSTAM ET AL.

Examiner

Howard V Owens

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 5-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____. |

Response to Arguments

The following is in response to the amendment filed 7-16-02:

An action on the merits of claims 5-16 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 5-16 are rejected under 35 U.S.C. § 103 as being unpatentable over Montgomery et al., U.S. Patent No. 4,357,324.

Claims 5-16 are drawn to Fludarabine-phosphate with a purity ranging from at least 99.5% – 99.85%.

Montgomery discloses the same compound, Fludarabine-phosphate or 9-(5-O-phosphate- β -D-arabinofuranosyl)-2-fluoroadenine (claim 4 or columns 2-4). Montgomery isolates the Fludarabine-phosphate from other contaminants via HPLC (col.4, lines 4-6) with subsequent anion exchange chromatography purification. However, Montgomery does not specifically state that the purity of the compound was greater than 99.5%.

Although Montgomery does not specifically state the purity, one of skill in the art would have a reasonable expectation of success in the attainment of a purity of at least 99.5, post HPLC and ion-exchange purification steps. Moreover, one could easily repeat these steps to obtain even higher purity if desired.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to obtain the highest purity available or that commensurate to 99% or better.

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A person of ordinary skill in the art would have been motivated to produce Fludarabine-phosphate at a purity of 99.5% or better to achieve the greatest anti-tumor efficacy. One of skill in the art would have had a reasonable expectation of success in the achievement of this purity given that the isolation of the compound had already been demonstrated in the prior art through routine purification techniques.

When claiming a purer form of a known compound, it must be demonstrated that the purified material possess properties and utilities not possessed by the unpurified material, *Ex parte Reed*, 135 USPQ 34,36 (P.O.B.A. 1961). Furthermore, there exists a vast number of decisions holding that where the purification of an old product results in a mere change in its properties, the purified form is unpatentable, *Ex parte Windhaus*, 15 USPQ 45 (POBA 1931); *In re Ridgeway*, 76 F.2d 602, 25 USPQ 202 (CCPA 1935); *In re Merz*, 97 F.2d 599, 38 USPQ 143 (CPA 1938). The claims of the invention do not possess properties and utilities not possessed by the fludara compound disclosed in Montgomery. Applicant has asserted that the highest purity that could be obtained by Montgomery is 99.19%. There is only a .03% difference between that of Montgomery and the claimed purity, which is so insignificant that taking into account experimental error, the claimed composition remains obvious.

For the reasons cited above, the 35 U.S.C. 103 rejection of record is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Howard V. Owens
Patent Examiner
Art Unit 1623

A handwritten signature in black ink, appearing to read "James O. Wilson", written over a horizontal line.

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.